

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|--|-------------------------------|--------------------|
| Substitute for form 1449/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Application Number | 10/550,165 |
| (use as many sheets as necessary) | | Filing Date | July 21, 2006 |
| Sheet 1 of 1 | | First named Inventor | Paul B. Savage |
| | | Group Art Unit | 1623 |
| | | Examiner name | Ganapathy Krishnan |
| | | Attorney Docket Number | 017968-9010 US00 |

U.S. Patent Documents

| Examiner Initials | | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
|-------------------|--|-----------------------------|---|---------------------------------------|
| /G.K./ | | 5,767,092 | Koezuka et al. | 6/16/1998 |
| | | 6,531,453 | Taniguchi et al. | 3/11/2003 |
| | | 6,747,010 | Taniguchi et al. | 6/8/2004 |
| | | 2002/0115624 | Behar et al. | 8/22/2002 |
| | | 2003/0139351 | Yagita | 8/14/2003 |
| | | 2003/0153514 | Yagita | 8/14/2003 |
| | | 2004/0266726 | Yagita | 12/30/2004 |
| | | 2006/0073118 | Bendelac et al. | 4/6/2006 |
| | | 2008/0095787 | Teyton | 4/24/2008 |
| /G.K./ | | 11/814103 | Teyton et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | | Country Code | Foreign Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Translation | English Abstract |
|-------------------|--|--------------|--------------------------------|---|---------------------------------------|-------------|------------------|
| /G.K./ | | WO | 2005/000348 | ISIS Innovation et al. | 1/6/2005 | | |
| | | WO | 2006/083671 | Brigham Young University et al. | 8/10/2006 | | |
| | | WO | 2007/118234 | The Scripps Research Institute et al. | 10/18/2007 | | |
| /G.K./ | | WO | 2008/005824 | The Scripps Research Institute et al. | 1/10/2008 | | |
| | | | | | | | |

| | | | |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Ganapathy Krishnan/ | Date Considered | 09/09/2009 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB number.

| | | | | | |
|---|---|----|---|--------------------------|--------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | 10/550,165 |
| Sheet | 1 | of | 4 | Filing Date | July 21, 2006 |
| | | | | First Named Inventor | Paul B. Savage |
| | | | | Group Art Unit | 1623 |
| | | | | Examiner Name | Ganapathy Krishnan |
| | | | | Attorney Docket Number | 017968-9010 US00 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|--|--|--|--|--|
| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. | | | |
| /G.K./ | | ANDO, H. et al., "Solid-phase capture-release strategy applied to oligosaccharide synthesis on a soluble polymer support," <i>Angew. Chem. Int. Ed.</i> (2001) 40:4725-4728 | | | |
| | | BENDELAC, A. et al., "Increased interleukin 4 and immunoglobulin E production in transgenic mice overexpressing NK1 T cells," <i>J. Exp. Med.</i> (1996) 184:1285-1293 | | | |
| | | BRIGL, M. et al., "CD1: T cell function and antigen presentation," <i>Annu. Rev. Immunol.</i> (2004) 22:817-890 | | | |
| | | BRIGL, M. et al., "Mechanism of CD1d-restricted natural killer T cell activation during microbial infection," <i>Nat. Immunol.</i> (2003) 4:1230-1237 | | | |
| | | CANTU, C. et al., "The paradox of immune molecular recognition of alpha-galactosylceramide: low affinity, low specificity for CD1d, high affinity for alpha beta TCRs," <i>J. Immunol.</i> (2003) 170:4673-4682 | | | |
| | | FUJII, S-I. et al., "Activation of natural killer T cells by alpha-galactosylceramide rapidly induces the full maturation of dendritic cells in vivo and thereby acts as an adjuvant for combined CD4 and CD8 T cell immunity to a coadministered protein," <i>J. Exp. Med.</i> (2003) 198:267-279 | | | |
| | | GARRITY, G.M. et al., Taxonomic Outline of the Prokaryotic Genera, <i>Bergey's Manual of Systematic Bacteriology</i> , 2nd Edition (April 2001) | | | |
| | | GODFREY, D.I. et al., "Going both ways: immune regulation via CD1d-dependent NKT cells," <i>J. Clin. Invest.</i> (2004) 114(10):1379-1388 | | | |
| /G.K./ | | GODFREY, D.I. et al., "The elusive NKT cell antigen - is the search over?" <i>Science</i> (2004) 306:1687-1688 | | | |

| | | | |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Ganapathy Krishnan/ | Date Considered | 09/09/2009 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

| | | | | | |
|--|---|----|---|--------------------------|--------------------|
| Substitute for form 1449B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/550,165 |
| (use as many sheets as necessary) | | | | Filing Date | July 21, 2006 |
| | | | | First Named Inventor | Paul B. Savage |
| | | | | Group Art Unit | 1623 |
| | | | | Examiner Name | Ganapathy Krishnan |
| Sheet | 2 | of | 4 | Attorney Docket Number | 017968-9010 US00 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|--|--|--|--|--|
| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. | | | |
| /G.K./ | | GOFF, R.D. et al., "Effects of lipid chain lengths in alpha-galactosylceramides on cytokine release by natural killer T cells," J. Am. Chem. Soc. (2004) 126:13602-13603 | | | |
| | | GUI, M. et al., "TCR beta chain influences but does not solely control autoreactivity of V alpha 14J28IT cells," J. Immunol. (2001) 167(11):6239-6246 | | | |
| | | GUMPERZ, J.E. et al., "Functional distinct subsets of CD1d-restricted natural killer T cells revealed by CD1d tetramer staining," J. Exp. Med. (2002) 195(5):625-636 | | | |
| | | HERMANS, I.F. et al., "NKT cells enhance CD4+ and CD8+ T cell responses to soluble antigen in vivo through direct interaction with dendritic cells," J. Immunol. (2003) 171:5140-5147 | | | |
| | | IIDA, N. et al., "A sulfated glucosylceramide from rat kidney," J. Biol. Chem. (1989) 264(10):5974-5980 | | | |
| | | ISMAIL, N. et al., "Overproduction of TNF-alpha b CD8+ type 1 cells and down-regulation of IFN- γ production by CD4+ Th1 cells contribute to toxic shock-like syndrome in an animal model of fatal monocytotropic ehrlichiosis," J. Immunol. (2004) 172:1786-1800 | | | |
| | | KARADIMITRIS, A. et al., "Human CD1d-glycolipid tetramers generated by in vitro oxidative refolding chromatography," Proc. Natl. Acad. Sci. USA (2001) 98(6):3294-3298 | | | |
| | | KINJO, Y. et al., "Recognition of bacterial glycosphingolipids by natural killer T cells," Nature (2005) 434:520-525 | | | |
| /G.K./ | | KRONENBERG, M., "Toward an understanding of NKT cell biology: progress and paradoxes," Ann. Rev. Immunol. (2005) 23:877-900 | | | |

| | | | |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Ganapathy Krishnan/ | Date Considered | 09/09/2009 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

| | | | | | |
|---|---|----|---|--------------------------|--------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | 10/550,165 |
| Sheet | 3 | of | 4 | Filing Date | July 21, 2006 |
| | | | | First Named Inventor | Paul B. Savage |
| | | | | Group Art Unit | 1623 |
| | | | | Examiner Name | Ganapathy Krishnan |
| | | | | Attorney Docket Number | 017968-9010 US00 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | |
|--|--|--|
| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |
| /G.K./ | | LEE, P.T. et al., "Testing the NKT cell hypothesis on human IDDM pathogenesis," <i>J. Clin. Invest.</i> (2002) 110(6):793-800 |
| | | MATTNER, J. et al., "Exogenous and endogenous glycolipid antigens activate NKT cells during microbial infections," <i>Nature</i> (2005) 434:525-529 |
| | | MATSUDA, J.L. et al., "Tracking the response of natural killer T cells to a glycolipid antigen using CD1d tetramers," <i>J. Exp. Med.</i> (2000) 192(5):741-753 |
| | | PETROVSKY, N. et al., "Vaccine adjuvants: current state and future trends," <i>Immunol. Cell Biol.</i> (2004) 82:488-496 |
| | | ROCK, K.L. et al., "Natural endogenous adjuvants," <i>Springer Semin. Immunopathol.</i> (2005) 26:231-246 |
| | | SIDOBRE, S. et al., "CD1d tetramers: a powerful tool for the analysis of glycolipid reactive T cells," <i>J. Immunol. Methods</i> (2002) 268:107-121 |
| | | VAN KAER, L., "Alpha-galactosylceramide therapy for autoimmune diseases: prospects and obstacles," <i>Nat. Rev. Immunol.</i> (2005) 5:31-42 |
| | | WU et al., "Bacterial glycolipids and analogs as antigen for CD1d-restricted NKT cells," <i>PNAS</i> (2005) 102(5):1351-1356 |
| /G.K./ | | ZAJONC, D.M. et al., "Structure and function of a potent agonist for the semi-invariant natural killer T cell receptor," <i>Nat. Immunol.</i> (2005) 6:810-818 |

| | | | |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Ganapathy Krishnan/ | Date Considered | 09/09/2009 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB number.

| | | | | | |
|--|---|----|---|--------------------------|--------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/550,165 |
| (use as many sheets as necessary) | | | | Filing Date | July 21, 2006 |
| Sheet | 4 | of | 4 | First Named Inventor | Paul B. Savage |
| | | | | Group Art Unit | 1623 |
| | | | | Examiner Name | Ganapathy Krishnan |
| | | | | Attorney Docket Number | 017968-9010 US00 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | |
|--|--|---|
| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |
| /G.K./ | | ZHOU, D. et al., "Lysosomal glycosphingolipid recognition by NKT cells," Science (2004) 306:1786-1789 |
| | | International Search Report and Written Opinion of International Searching Authority of PCT/US2007/072451 dated November 27, 2007 |
| | | International Search Report and Written Opinion of International Searching Authority of PCT/US06/002781 dated December 20, 2006 |
| | | Supplementary Search Report of the European Patent Office for Application No. 03816701.1 dated September 17, 2007 |
| | | European Office Action for Application No. 03816701.1 dated November 29, 2007 |
| | | Written Opinion of International Preliminary Examining Authority for International Application No. PCT/US03/08530 dated June 30, 2005 |
| | | International Search Report of International Searching Authority for Application No. PCT/US03/08530 dated August 3, 2004 |
| /G.K./ | | International Search Report and Written Opinion of International Searching Authority for International Application No. PCT/US07/66250 dated October 15, 2007 |

| | | | |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Ganapathy Krishnan/ | Date Considered | 09/09/2009 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.